USING INTERACTIVE VIRTUAL PRESENCE TO REMOTELY ASSIST PARENTS WITH CHILD RESTRAINT INSTALLATIONS

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STATEMENT OF COMPLIANCE

The trial will be conducted in accordance with International Conference on Harmonisation Good Clinical Practice (ICH GCP) and applicable United States (US) Code of Federal Regulations (CFR). The Principal Investigator will assure that no deviation from, or changes to, the protocol will take place without prior documented approval from the Institutional Review Board (IRB), except where necessary to eliminate an immediate hazard(s) to the trial participants. All personnel involved in the conduct of this study have completed Human Subjects Protection and ICH GCP Training.

The protocol, informed consent form(s), recruitment materials, and all participant materials will be submitted to the local Institutional Review Board (IRB) for review and approval. Approval of both the protocol and the consent form must be obtained before any participant is enrolled. Any amendment to the protocol will require review and approval by the IRB before the changes are implemented to the study. All changes to the consent form will be IRB approved; a determination will be made regarding whether a new consent needs to be obtained from participants who provided consent, using a previously approved consent form.

1 PROTOCOL SUMMARY

1.1 SYNOPSIS

Title:	Using Interactive Virtual Presence to Remotely Assist Parents with Child Restraint Installations
Study Background:	Motor vehicle crashes are the third-leading cause of death to American children ages 1-5. When installed correctly, child restraints (car seats) reduce risk of serious injury and death. However, most restraints are installed incorrectly. The current gold standard for correct installation is systematic car seat checks, where certified technicians help parents, but car seat checks are highly underutilized due to barriers in access, scheduling, and resources. The present study evaluates use of interactive virtual presence technology (interactive merged reality) – joint, simultaneous remote verbal and visual interaction and exposure to the same 3D stimuli – to assist remotely-located parents installing child restraints. If effective, this technology could supplement or replace in-person checks and revolutionize how government, industry, and non-profits help parents install child restraints properly.
Objectives:	This protocol describes a randomized non-inferiority trial to evaluate whether parents who install child restraints while communicating with remote expert technicians via interactive virtual presence on their smartphones achieve installations and learning not inferior in safety to parents who install restraints with on-site technicians.
Study Population:	Caregivers of children who have child restraints in a vehicle
Phase:	III
Description of Study Intervention:	Remote assistance with installation of child restraints in vehicles

2 INTRODUCTION

2.1 STUDY RATIONALE

Motor vehicle crashes are the third-leading cause of death for American children ages 1-5 years. Morbidity rates far exceed mortality and impact public health tremendously. In 2017, over 500 American children age 5 years and under were killed in motor vehicle crashes and over 37,000 others were injured seriously enough to visit an emergency department. Child restraints are documented to provide excellent protection to risk morbidity and mortality to children in motor vehicle crashes. However, child restraints are frequently installed incorrectly by caregivers. This study investigates the potential to use interactive virtual presence to remotely assist parents with installation of child restraints, offering a means to reach caregivers efficiently and broadly with valuable assistance to install child restraints correctly.

2.2 BACKGROUND

Child restraint systems

Child restraint systems (also called “restraints” and “car seats”) reduce risk of serious injury and death to infants and young children roughly threefold, but are most effective when installed correctly. Unfortunately, multiple studies suggest a large portion of child restraints are installed incorrectly. It is unclear exactly why child restraints are installed incorrectly with such frequency. One factor may be that manufacturer instruction manuals are difficult to comprehend or are not reviewed carefully by parents. Another explanation is the physical demands required to complete the task of installing a child restraint. Ergonomic research documents the fact that proper installation of child restraints requires some degree of strength and agility, especially if the installer is unfamiliar with optimal installation strategies. A third factor is that installation is simply very difficult. Correct installation often requires assistance from an expert.

Increasing the rate of correctly-installed child restraints

Individualized one-on-one installation of child restraints is considered the gold standard for child safety, but available evidence concerning incorrect installation rates and appointments at certified car-seat inspection stations and car seat checks (also called check-up events) suggest it is practiced infrequently.

There are several barriers to use of car seat checks. One is convenience. Many families with young children live busy, chaotic, and/or stressful lives and the task of obtaining, remembering, and attending an appointment for a car seat check may fall low in the list of household priorities. Another is access. Organizing and staffing car seat checks with certified technicians is expensive for government or non-profit agencies to administer. Demand greatly outpaces supply in most locations, and access is particularly poor in rural areas of the country. The present study will evaluate whether we might overcome barriers through use of mobile interactive virtual presence that permits remotely-located certified technicians to interact with parents to install child restraints in their vehicles at convenient times and places using a mobile smartphone.

Interactive virtual presence

Recent technological advances in interactive virtual presence – technology that integrates augmented and merged virtual reality to permit remote experts to train lay or professional individuals – suggests it

can be effective in a wide variety of tasks through joint exposure to 3D images and interactive simultaneous engagement with the object(s) of interest. For example, a remotely located machinist can help a laborer repair the electrical circuit on a complex piece of factory equipment without traveling on-site for repairs.

In technical language, interactive virtual presence refers to the opportunity for users to simultaneously engage in interactive visual, nonverbal and aural communication. It provides merged reality and concurrent virtual interaction. Users can instantly and simultaneously view and merge two real-time perspectives, offering opportunity for remote collaboration while interactively examining, pointing to, grasping, illustrating and discussing a video stream. Images can be frozen, drawn upon, animated, and viewed live. Interactive virtual presence can be delivered through a range of hardware platforms, including tablets and mobile smartphones.

In lay language, interactive virtual presence implies that users requiring help – in the case of our research, parents – may place their smartphone over a targeted area to allow the expert – in our case, a remotely-located certified technician – to "freeze" that image and then point to or grasp particular areas with their hands and/or with telestration tools like arrows and pointers located within the software while speaking. Thus, for example, if a parent was unsure where to connect a child restraint anchor, she could use her smartphone to show the technician the back seat of the car and request that the technician point with her finger to the location of the anchor. Similarly, a parent could direct his phone's camera toward a child restraint to verify it is installed well and the technician might notice a loose strap, draw a circle around that strap, and request that the parent tighten it. Interactive virtual presence extends beyond traditional telemedicine and video chat, instead providing the opportunity to engage immersively in all tasks and activities that a live certified technician provides, but using technology from a remote location.

The cognitive and behavioral bases of child restraint installation

Installing a child restraint properly is a challenging task that requires complex cognitive processing and logical thinking, some degree of physical strength and dexterity, patience and persistence, and practice and training. Empirical research consistently demonstrates that parents are poor at the task when they engage in it without any resources or with only the manufacturer's instruction manual.

The best alternative strategy to self-installation, and the recommendation of both pediatricians and traffic safety experts, is use of individualized instruction, education and assistance from a currently certified technician. Recent evidence from a study of 291 parents, some of whom had recently worked with certified technicians to install their restraint, showed that parents who worked with technicians had 90% fewer critical misuse errors than parents who had not worked with technicians. Interactions with technicians may also have some lasting effect over time. Among one sample of 47 parents, interaction with a certified technician yielded a significant drop in any misuse of the restraint upon a 4-month follow-up (from 80% to 66%), as well as a significant drop in "critical" misuse (from 52% to 40%).

2.3 RISK/BENEFIT ASSESSMENT

2.3.1 KNOWN POTENTIAL RISKS

Physical risk includes (a) minor risk of discomfort or injury while installing a child restraint and (b) minor risk of discomfort from heat while installing a car seat in an outdoor setting during hot weather.

Psychological risks include (a) embarrassment from engaging in the research protocol, which involves physical movement in the back seat of a vehicle, and (b) embarrassment to answer questionnaires that are mildly invasive, such as household income.

There is minimal social risk from participating in this study. The primary risk results from the possibility for a breach of confidentiality. No data we collect will be highly personal, but we will collect information that participants may wish to keep private (such as household income), and the risk of a confidentiality breach is a social risk.

Participants will use their own smartphone to participate in the study and in some cases may incur small costs to use their phone. There are no known legal risks involved in study participation.

2.3.2 KNOWN POTENTIAL BENEFITS

Study results may provide valuable information to reduce risk of child injury or death in motor vehicle crashes. Study participants will have their child restraints installed with assistance from certified technicians.

3 STUDY DESIGN

3.1 OVERALL DESIGN

A non-inferiority randomized controlled trial will be conducted.

4 STUDY POPULATION

4.1 INCLUSION CRITERIA

- Individuals who frequently drive children in their vehicles
- Live in broad geographic footprint of participating Safe Kids Worldwide data collection center: Safe Kids Alabama/Children's Health System (based in Birmingham, AL); Safe Kids California, Los Angeles/Los Angeles Children's Hospital (based in Los Angeles, CA); Safe Kids Charlotte/Mecklenburg/Carolinas Medical Center (based in Charlotte, NC); Safe Kids Oklahoma/The Children's Center Rehabilitation Hospital (based in Oklahoma City, OK); Safe Kids Greater Houston (based in Houston, TX); Safe Kids Vermont/University of Vermont Children's Hospital (based in Burlington, VT); and Safe Kids Lower Columbia/Cowlitz County EMS and Trauma Care Council (based in Kelso, WA)
- Access to smartphone or other internet-based device (e.g., tablet)

4.2 EXCLUSION CRITERIA

- Inability to communicate in English or Spanish
- Physical or mental disability that prohibits valid participation in the study

5 STUDY INTERVENTION

5.1 STUDY INTERVENTION(S) ADMINISTRATION

5.1.1 STUDY INTERVENTION DESCRIPTION

All visits will be conducted by two individuals, a researcher (who is also certified as a CPS technician) and a technician. Following baseline activities, the researcher will inform the participant of their random assignment to a condition, either installation with a certified technician via interactive virtual presence or installation via the traditional live technician interaction. In cases where there is more than one restraint in the vehicle, the researcher will use a random number generator to select one of the restraints as the target for the research.

Those parents randomly assigned to the interactive virtual presence condition will be instructed how to connect to the interactive virtual presence program using their personal smartphone. Participants will connect to the interactive virtual presence program, view a brief online instructional video on using it, and then connect remotely to a certified technician.

Ensuring ecological validity and pragmatic trial practice, the researcher and local technician will purposely "stay away" through the remote installation process, allowing the parent and remote technician to engage via interactive virtual presence to install the restraint correctly in the vehicle. Remote technicians will guide the interaction following standard Safe Kids Worldwide practice for live in-person installations and participants will physically install and adjust the restraint into their own vehicle.

Those parents assigned to the control condition, installation by a live technician, will engage in standard procedures at Safe Kids Worldwide car seat checks to install the target restraint into the vehicle. The live technician will not be the same individual as the researcher, although they will both be present at the same location during the research protocol.

5.2 MEASURES TO MINIMIZE BIAS: RANDOMIZATION

Randomization lists will be generated by the study biostatistician and stored electronically. A separate randomization list will be generated for each site and all will utilize a randomly permuted block design to allow for balance among intervention arms as the research study progresses and to limit the ability of any research staff member from definitively knowing/predicting future assignment. Block sizes will range over all even numbers from 8 to 16 inclusive.

6 STUDY INTERVENTION DISCONTINUATION AND PARTICIPANT DISCONTINUATION/WITHDRAWAL

6.1 DISCONTINUATION OF STUDY INTERVENTION

The intervention will be discontinued if participants request it or if the remote connection fails due to technology problems. Training will be discontinued also if there is any sign of adverse or iatrogenic effect.

6.2 PARTICIPANT DISCONTINUATION/WITHDRAWAL FROM THE STUDY

Participants are free to withdraw from participation in the study at any time upon request. An investigator may discontinue or withdraw a participant from the study for the following reasons:

- Non-compliance to study protocol
- If any clinical adverse event (AE), laboratory abnormality, or other medical condition or situation occurs such that continued participation in the study would not be in the best interest of the participant

6.3 LOST TO FOLLOW-UP

A participant will be considered lost to follow-up if they fail to attend scheduled visits and/or are unable to be contacted by the study site staff.

7 STUDY ASSESSMENTS AND PROCEDURES

7.1 STUDY ASSESSMENTS

We will consider two primary outcomes, both derived from inspections of child restraint installations using objective coding sheets: (a) total number of inspection points that are correctly installed, translated into a percentage to account for different points for different (e.g., rear-facing vs forward-facing; seat belt vs LATCH) installations, and (b) dichotomous measure of whether the restraint was installed correctly vs. not correctly. Examples of inspection points include whether tether straps are twisted, whether the seat moves more than 1 inch to the left/right, whether seat belts are routed through the correct belt pathway, and whether the carrying handle is in the correct position.

Both outcomes will be collected at four time points: at baseline prior to any intervention, at post, immediately following the initial installation in both groups, at the start of the follow-up visit following 4 months of no active intervention by the research team, and at follow-up after parent installation without technician assistance.

We also will consider results from a brief knowledge questionnaire, which was adopted from an existing instrument. Secondary and covariate measures considered will include demographic traits of the participant (e.g., gender, race, ethnicity, SES, research site) and restraint (e.g., forward vs rear facing, LATCH vs seat belt installation), attitudes and beliefs about child restraints, perceived efficacy of the interventions, and reported behaviors using restraints.

7.2 ADVERSE EVENTS AND SERIOUS ADVERSE EVENTS

7.2.1 DEFINITION OF ADVERSE EVENTS (AE)

Adverse event means any untoward medical occurrence associated with the use of an intervention in humans, whether or not considered intervention-related (21 CFR 312.32 (a)).

7.2.2 DEFINITION OF SERIOUS ADVERSE EVENTS (SAE)

An adverse event (AE) is considered “serious” if, in the view of either the investigator or sponsor, it results in any of the following outcomes:

- Death
- A life-threatening adverse event (of note, the term “life-threatening” refers to an event in which the participant was at risk of death at the time of the event, rather than to an event which hypothetically might have caused death if it were more severe)
- inpatient hospitalization or prolongation of existing hospitalization
- a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions
- or a congenital anomaly/birth defect.

Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered serious when, based upon appropriate medical judgment, they may jeopardize the participant and may require medical or surgical intervention to prevent one of the outcomes listed in this definition. Examples of such medical events include allergic bronchospasm requiring intensive treatment in an emergency room or at home, blood dyscrasias or convulsions that do not result in inpatient hospitalization, or the development of drug dependency or drug abuse.

7.2.3 CLASSIFICATION OF AN ADVERSE EVENT

7.2.3.1 SEVERITY OF EVENT

For adverse events (AEs), the following guidelines will be used to describe severity:

- **Mild** – Events require minimal or no treatment and do not interfere with the participant’s daily activities.
- **Moderate** – Events result in a low level of inconvenience or concern with the therapeutic measures. Moderate events may cause some interference with functioning.
- **Severe** – Events interrupt a participant’s usual daily activity and may require systemic drug therapy or other treatment. Severe events are usually potentially life-threatening or incapacitating. Of note, the term “severe” does not necessarily equate to “serious.”

7.2.3.2 RELATIONSHIP TO STUDY INTERVENTION

All adverse events (AEs) must have their relationship to study intervention assessed by the researchers who examine and evaluate the participant based on temporal relationship and his/her clinical judgment. The degree of certainty about causality will be graded using the categories below. In a clinical trial, the study product must always be suspect.

- **Related** – The AE is known to occur with the study intervention, there is a reasonable possibility that the study intervention caused the AE, or there is a temporal relationship between the study intervention and event. Reasonable possibility means that there is evidence to suggest a causal relationship between the study intervention and the AE.
- **Not Related** – There is not a reasonable possibility that the administration of the study intervention caused the event, there is no temporal relationship between the study intervention and event onset, or an alternate etiology has been established.

7.2.3.3 EXPECTEDNESS

The Principal Investigator will be responsible for determining whether an adverse event (AE) is expected or unexpected. An AE will be considered unexpected if the nature, severity, or frequency of the event is not consistent with the risk information previously described for the study intervention.

7.2.4 TIME PERIOD AND FREQUENCY FOR EVENT ASSESSMENT AND FOLLOW-UP

The occurrence of an adverse event (AE) or serious adverse event (SAE) may come to the attention of study personnel during study visits and interviews of a study participant, or upon review by a study monitor.

All AEs including local and systemic reactions not meeting the criteria for SAEs will be captured on the appropriate case report form (CRF). Information to be collected includes event description, time of onset, assessment of severity, relationship to study activities, and time of resolution/stabilization of the event. All AEs occurring while on study will be documented appropriately regardless of relationship. All AEs will be followed to adequate resolution.

7.2.5 ADVERSE AND SERIOUS ADVERSE EVENT REPORTING

All serious adverse events will be reported to the IRB according to regulatory requirements. The Principal Investigator will report to the sponsor any serious adverse event in a timely manner. All serious adverse events (SAEs) will be followed until satisfactory resolution.

7.3 UNANTICIPATED PROBLEMS

7.3.1 DEFINITION OF UNANTICIPATED PROBLEMS (UP)

The Office for Human Research Protections (OHRP) considers unanticipated problems involving risks to participants or others to include, in general, any incident, experience, or outcome that meets **all** of the following criteria:

- Unexpected in terms of nature, severity, or frequency given (a) the research procedures that are described in the protocol-related documents, such as the Institutional Review Board (IRB)-approved research protocol and informed consent document; and (b) the characteristics of the participant population being studied;
- Related or possibly related to participation in the research ("possibly related" means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and
- Suggests that the research places participants or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

7.3.2 UNANTICIPATED PROBLEM REPORTING

The investigator will report unanticipated problems (UPs) to the reviewing Institutional Review Board (IRB). The UP report will include the following information:

- Protocol identifying information: protocol title and number, PI's name, and the IRB project number;
- A detailed description of the event, incident, experience, or outcome;
- An explanation of the basis for determining that the event, incident, experience, or outcome represents an UP;

- A description of any changes to the protocol or other corrective actions that have been taken or are proposed in response to the UP.

To satisfy the requirement for prompt reporting, UPs will be reported using the following timeline:

- UPs that are serious adverse events (SAEs) will be reported to the IRB within 10 working days of the investigator becoming aware of the event.
- Any other UP will be reported to the IRB within 10 working days of the investigator becoming aware of the problem.

8 STATISTICAL CONSIDERATIONS

8.1 STATISTICAL HYPOTHESES

- Primary Endpoint(s):

(a) total number of inspection points that are correctly installed, translated into a percentage to account for different points for different (e.g., rear-facing vs forward-facing; seat belt vs LATCH) installations, and (b) dichotomous measure of whether the restraint was installed correctly vs. not correctly

- Secondary Efficacy Endpoint(s):

results from a brief knowledge questionnaire

8.2 SAMPLE SIZE DETERMINATION

To conclude non-inferiority of the interactive remote presence condition with ≥80% power, Type I error rate of .025, a non-inferiority margin of 0.025, and assuming a common SD of 0.10 (similar to that observed previously), we propose a sample size of 1476. This estimate conservatively assumes 10% attrition based on a two-sample test of non-inferiority difference in means.

The table below presents statistical power to declare non-inferiority between two means, as defined by the alternative hypothesis, assuming a common standard deviation of 0.10, a Type I error rate of 0.025, a sample size per group of 664, the non-inferiority margin (Δ) specified in the row, and the different combinations of intervention means ($\mu 1$, $\mu 2$) specified by the columns. As long as the difference between the two means is less than the assumed non-inferiority margin, the definition of non-inferiority is met and power can be calculated. However, as can be seen by each row of the table, as the difference in intervention means grows, statistical power will decrease.

To illustrate interpretation of the table, if the mean installation accuracy of in-person instruction is 0.90 and the mean installation accuracy of remote instruction is 0.90 (i.e., the two groups achieve equal accuracy), then 664 persons randomized to each group provides 99.5% power to declare non-inferiority of remote instruction to in-person instruction using a Type I error rate of .025, a non-inferiority margin of 0.025, and a common standard deviation of 0.10. Similarly, if the mean installation accuracy of in-person instruction is 0.90 and the mean installation accuracy of remote instruction is 0.89, the two means are not equal but the difference in means (0.90-0.89 = 0.01) remains less than the declared non-inferiority margin (0.025). Under this scenario, 664 persons randomized to each group provides 78% power to declare non-

inferiority of remote instruction to in-person instruction using a Type I error rate of .025, a non-inferiority margin of 0.025, and a common standard deviation of 0.10.

Table. Statistical Power assuming 664 persons randomized per group (total N = 1476 with conservatively-estimated 10% attrition).

	Combination of mean accuracy scores for intervention groups				
Δ	μ1 = 0.90 μ2 = 0.90	μ1 = 0.90 μ2 = 0.8975	μ1 = 0.90 μ2 = 0.895	μ1 = 0.90 μ2 = 0.8925	μ1 = 0.90 μ2 = 0.8900
0.020	0.954	0.890	0.780	0.625	0.445
0.025	0.995	0.984	0.954	0.890	0.780
0.030	0.999	0.999	0.995	0.984	0.954

8.3 STATISTICAL ANALYSES

Descriptive Statistics and Covariates. Descriptive statistics for participants randomized to each intervention will be summarized for each outcome using measures of central tendency (mean, median, proportion) and variability (variance, standard deviation, range). Several covariates may impact the relation between the intervention and the outcome measures of interest, and they will be similarly summarized descriptively. These include demographics (age, gender, target child birth order, race, ethnicity, SES); study site; type of vehicle; type of child restraint (including forward- vs. rear-facing); and attitudes, beliefs, and behaviors surrounding child restraints. Because parents will be randomized to the interventions, we expect covariates to be balanced across intervention groups. We will assess balance across intervention groups and utilize covariates in the primary analyses if appropriate. We also will estimate interaction effects to determine whether the intervention is more or less effective among particular subgroups that are adequately represented in the sample.

Primary Analyses. We have three specific aims. Specific Aim 1 is to identify how accurate parents are at installing child restraints using instructions from technicians via interactive virtual presence. We expect to find over 90% or greater of restraints are installed correctly in all respects. We also will investigate individual components of installation and expect over 90% of components, across participants, will be installed correctly. 95% confidence intervals for all of these outcomes will be calculated and presented graphically as a Forrest Plot with a reference line set at 0.90. Identical analyses will be conducted for the group randomized to in-person installation.

Specific Aim 2 will test whether child restraint installation by interactive virtual presence achieves installation accuracy at a rate not inferior to installation with a live technician. Two models will be computed, one with a measure of installation accuracy (proportion of all child restraint installation components performed correctly) as the dependent variable and the other with the dichotomous outcome of correct (100% correct installation across all components) vs. incorrect installation (<100% correct installation) as the dependent variable. Assuming that improvement is reflected by a positive value (that is, a higher post-training value is better), our primary model, based upon installation accuracy, is:

H_o: $\Delta_{LIVE} - \Delta_{IVP} \geq \delta$ vs. H_A: $\Delta_{LIVE} - \Delta_{IVP} < \delta$

where δ is the non-inferiority margin and IVP stands for interactive virtual presence. We will assume a non-inferiority margin of 0.025 for the primary analysis (see power analysis) and perform Analysis of

Covariance (ANCOVA) to determine if the difference of mean installation accuracy scores between the two groups falls below the non-inferiority margin of 0.025, after adjustment for the baseline measure of installation accuracy and other relevant covariates. Based on previous work, we do not anticipate non-normality of the continuous outcome variable of installation accuracy. However, we will assess normality using graphical techniques (normal probability plot, histograms) prior to analysis and will transform outcomes if appropriate. The one-sided non-inferiority test will be conducted using a Type I error of 0.025.

Specific Aim 3 will test parent learning and retention, both through measures of installation accuracy (after the intervention, at start of follow-up visit, and after parent re-installation during follow-up visit) and through the brief knowledge questionnaire administered at post and at follow-up. Six models will be computed using strategies identical to those for Aim 2 and predicting the following dependent variables: (a) installation accuracy (proportion of restraint components performed correctly at start of 4-month follow-up visit); (b) dichotomous outcome of correct vs incorrect installation at start of follow-up visit; (c) installation accuracy after parental re-installation during follow-up visit; (d) dichotomous outcome of correct vs incorrect installation after parental re-installation during follow-up visit; (e) knowledge questionnaire during post visit; and (f) knowledge questionnaire during follow-up visit.

9 SUPPORTING DOCUMENTATION AND OPERATIONAL CONSIDERATIONS

9.1 REGULATORY, ETHICAL, AND STUDY OVERSIGHT CONSIDERATIONS

9.1.1 INFORMED CONSENT PROCESS

9.1.1.1 CONSENT/ASSENT AND OTHER INFORMATIONAL DOCUMENTS PROVIDED TO PARTICIPANTS

Consent forms describing in detail the study intervention, study procedures, and risks are given to participants parents and documentation of informed consent is required prior to conducting study activities.

9.1.1.2 CONSENT PROCEDURES AND DOCUMENTATION

Informed consent is a process that is initiated prior to the individual's agreeing to participate in the study and continues throughout the individual's study participation. Consent forms will be Institutional Review Board (IRB)-approved and participants will be asked to read and review the document. The investigator will answer any questions that arise in terms suited to the participant's comprehension. Participants will have the opportunity to carefully review the written consent form and ask questions prior to signing. The participant will sign the informed consent document prior to engaging in any study procedures. Participants will be informed that participation is voluntary and that they may withdraw from the study at any time, without prejudice. The informed consent process will be conducted and documented in the source document (including the date).

9.1.2 STUDY DISCONTINUATION AND CLOSURE

This study may be temporarily suspended or prematurely terminated if there is sufficient reasonable cause. Written notification, documenting the reason for study suspension or termination, will be provided by the suspending or terminating party to regulatory authorities. If the study is prematurely terminated or suspended, the Principal Investigator (PI) will promptly inform study participants and the Institutional Review Board (IRB), will provide the reason(s) for the termination or suspension. Study participants will be contacted, as applicable, and be informed of changes to study visit schedule.

Circumstances that may warrant termination or suspension include, but are not limited to:

- Determination of unexpected, significant, or unacceptable risk to participants
- Demonstration of efficacy that would warrant stopping
- Insufficient compliance to protocol requirements
- Data that are not sufficiently complete and/or evaluable
- Determination of futility

The study may resume once concerns about safety, protocol compliance, and data quality are addressed, and satisfy the IRB.

9.1.3 CONFIDENTIALITY AND PRIVACY

Participant confidentiality and privacy is strictly held in trust by the participating investigators and their staff. Therefore, study documentation, data, and all other confidential information generated will be held in strict confidence. No information concerning data will be released to any unauthorized third party without prior written approval of the Principal Investigator.

Representatives of the Institutional Review Board (IRB) may inspect all documents and records required to be maintained by the investigator.

Study participants' contact information will be securely stored for internal use during the study. At the end of the study, all records will continue to be kept in a secure location for as long a period as dictated by the reviewing IRB and/or Institutional policies.

Study participant research data, which is used for purposes of statistical analysis and scientific reporting, will be stored securely. Individual participant research data will be identified by a unique study identification number.

9.1.4 DATA HANDLING AND RECORD KEEPING

9.1.4.1 DATA COLLECTION AND MANAGEMENT RESPONSIBILITIES

Data collection is the responsibility of the research team under the supervision of the Lab Manager, Study Biostatistician, and Principal Investigator. The Principal Investigator is responsible for ensuring the accuracy, completeness, legibility, and timeliness of the data reported.

9.1.4.2 STUDY RECORDS RETENTION

Study documents will be retained for a minimum of 3 years after the completion of the study or longer if required by local regulations.

9.1.5 PROTOCOL DEVIATIONS

A protocol deviation is any noncompliance with the clinical trial protocol requirements. The noncompliance may be either on the part of the participant, the investigator, or the study site staff. As a result of deviations, corrective actions will developed and implemented.

These practices are consistent with ICH GCP:

- 4.5 Compliance with Protocol, sections 4.5.1, 4.5.2, and 4.5.3
- 5.1 Quality Assurance and Quality Control, section 5.1.1
- 5.20 Noncompliance, sections 5.20.1, and 5.20.2.

It is the responsibility of the Principal Investigator to use continuous vigilance to identify and report deviations within 10 working days of identification of the protocol deviation. Protocol deviations must be sent to the reviewing Institutional Review Board (IRB) per their policies. The Principal Investigator is responsible for knowing and adhering to the reviewing IRB requirements.

9.2 ABBREVIATIONS

AE	Adverse Event
ANCOVA	Analysis of Covariance
CFR	Code of Federal Regulations
CONSORT	Consolidated Standards of Reporting Trials
CRF	Case Report Form
DHHS	Department of Health and Human Services
GCP	Good Clinical Practice
HIPAA	Health Insurance Portability and Accountability Act
ICH	International Conference on Harmonisation
ICMJE	International Committee of Medical Journal Editors
IRB	Institutional Review Board
LSMEANS	Least-squares Means
NCT	National Clinical Trial
NIH	National Institutes of Health
OHRP	Office for Human Research Protections
PI	Principal Investigator
QA	Quality Assurance
QC	Quality Control
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SOA	Schedule of Activities
SOP	Standard Operating Procedure
UP	Unanticipated Problem
US	United States

10 REFERENCES

Much of this protocol was published in the following study protocol:

Schwebel, D. C., Mackay, J. M., & Redden, D. (2020). Study protocol: A randomized non-inferiority trial using interactive virtual presence to remotely assist parents with child restraint installations. *Injury Prevention, 26*, 289-294.

Other aspects are included in the study IRB protocol.